



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/089,776 | 06/21/2002 | Kei Tashiro | 29288.5600 | 2614 |

20322 7590 10/04/2006

SNELL & WILMER
400 EAST VAN BUREN
ONE ARIZONA CENTER
PHOENIX, AZ 85004-2202

EXAMINER

HAQ, SHAFIQU

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1641

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/089,776

Applicant(s)

TASHIRO ET AL.

Examiner

Shafiquel Haq

Art Unit

1641

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 September 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.



**LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**

Continuation of 3. NOTE: The incorporation of the phrase "subjecting biological fluid sample to heat treatment under denaturing temperature conditions of about 37C to about 55C" in claims 1 and 16 do not have support in the specification, and thus amended claims fails to comply with written description requirement. This also raises new issue (i.e. consideration of heat treatment at 37C to about 55C) that would require further consideration and/or search. .

Continuation of 11. does NOT place the application in condition for allowance because: Applicants' arguments and amendment have fully been considered but are not persuasive to place the application in a condition for allowance. Amended claims 1 and 16 recite the phrase "subjecting biological fluid sample to a heat treatment under denaturing temperature conditions of about 37C to about 55C". Specification does not have support for the denaturing temperature range of 37C to 55C. In remarks of 9/6/06, Applicants stated that heating at 37C or 55C for 30 minutes is in reference to analysis of SDF1 reference solution, not plasma samples and heating reference samples at 37C or 100C actually decreased the amount detected (see last paragraph of page 8 of Applicants' remarks). Applicants cited the same reference page (page 63, line 7 which disclose heating reference sample at 37C) to establish lower temperature range for heating plasma sample (i.e. lower temperature range for non-denaturing temperature). There is no clear teaching in the specification that heating at 37C leads to increased sensitivity of detection for biological fluid sample. However, as stated in 7/21/06 office action, specification has guidance and examples of heat treatment at 55C for 30 minutes that results in the enhancement in fluorescence intensity but there is no guidance and examples for other temperature conditions that resulted in improved sensitivity. The assertion "any temperature below 37C would not constitute heating" is not persuasive because any temperature that raises the temperature of a solution or an object above ground level could constitute heating. As for example a solution at 25C (i.e. room temperature) can be heated on a 30C water bath to raise the temperature to 30C and this would constitute heating. .